REMARKS

Claims 1-5, 7 and 8 were pending in the instant application. Claim 7 has been cancelled without prejudice. Claims 1, 2, 5, and 8 have been amended. New claims 14-19 have been added. Support for the claim amendments and new claims can be found throughout the specification and claims as originally filed. In particular, support for new claims 16-19 can be found in the specification at page 290, line 19, through page 261, line 12; and at page 261, line 25, through page 263, line 13. No new matter has been added.

Attached hereto is APPENDIX A, captioned "**VERSION WITH MARKINGS TO SHOW CHANGES MADE**", including a marked-up version of the changes made to the specification and claims 1, 2, 5 and 8 by the current amendment. Also attached hereto is APPENDIX B, including the full set of claims that will be pending after entry of the instant amendment.

Any amendment to the claims should in no way be construed as an acquiescence to any of the Examiner's rejections and was done solely to more particularly point out and distinctly claim the subject matter of Applicants' invention to expedite the prosecution of the application. Applicants reserve the right to pursue the claims as originally filed in this or in a separate application(s).

Priority

The Office Action (paragraph 4) indicates that priority has not been granted to the claimed provisional applications for the elected invention because it has not been

determined that the elected invention was disclosed in the claimed provisional applications. In response to the Examiner's objection, Applicants submit the following. The description of clone er311_20 in provisional application Serial No. 60/087,645, filed June 2, 1998, indicates 2644 nucleotides for SEQ ID NO:1 (renumbered SEQ ID NO:22 in the instant application) and 667 amino acid sequence for SEQ ID NO:2 (renumbered SEQ ID NO:23 in the instant application), which is consistent with the instant application and provides adequate support under 35 U.S.C. §112 for claims directed to certain full length er311_20 polynucleotides and/or proteins as well as claims to certain er311_20 fragments, vectors, host cells and methods. Moreover, priority for certain unclaimed embodiments is rightfully asserted for subject matter which Applicants intend to pursue in continuing applications. Accordingly, Applicants assert that the priority claim of the instant application is rightfully made and refusal to "grant" priority is inappropriate.

Claim Rejections Under 35 U.S.C. §101 and § 112, First Paragraph

Claims 1-5, 7 and 8 stand rejected under 35 U.S.C. §101 because, according to the Examiner, the claimed invention is not supported by a specific asserted utility or a substantial utility. Applicants respectfully disagree and traverse the foregoing rejection for the following reasons.

Claim 7 has been cancelled without prejudice, thereby obviating the rejection as to that claim. With respect to the presently pending claims, it is Applicants' position that a specific and substantial utility for the claimed invention is clearly set forth in the instant specification. Namely, the claimed nucleic acid molecules encode a human protein sharing a significant degree of sequence identity with the previously characterized mouse

kanadaptin protein. Mouse kanadaptin is an adapter protein that facilitates targeting of the anion exchanger, kAE1. The protein of the present invention is asserted to share the activities of mouse kanadaptin (see *e.g.*, the instant specification at page 198, lines 7-23). Based on these asserted activities, uses in modulating anion carrier targeting or screening for targeting molecules are readily apparent to the skilled artisan. In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection of the claims under 35 U.S.C. §101.

Claims 1-5, 7 and 8 are further rejected under 35 U.S.C. §112, first paragraph. The Office Action, at page 6, alleges that "since the claimed invention is not supported by either a specific and substantial utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention." Applicants respectfully traverse the foregoing rejection.

As indicated above with regard to the traversal of the rejection under 35 U.S.C. §101, the claimed invention has a specific and substantial utility. As discussed above, the claimed kanadaptin homologue is asserted to share the activities of mouse kanadaptin and, thus, would be useful for modulating anion exchanger targeting and/or for screening for modulators of such targeting. Applicants' specification and the state of the art at the time Applicants' invention was made provide *ample* guidance as to how one of ordinary skill in the art would use the claimed homologue-encoding nucleic acids to carry out these activities. The specification is replete with teachings as to how the skilled artisan would make proteins from the claimed nucleic acid molecules for use, for example, in screening assays, to make antibodies and the like (see *e.g.*, the specification at page 267, lines 1-13; and at page 287, line 29, through page 289, line 4). Accordingly,

reconsideration and withdrawal of the rejection of the claims under 35 U.S.C. §112, first paragraph, are respectfully requested.

Claims 1-5, 7 and 8 also stand rejected for lack of written description. In particular, the Examiner states that "because it is not apparent that SEQ ID NO:21 and 22 and clone er311_20 comprise a complete open reading frame, claims 1-5, 7, and 8 are drawn to encompass gene sequences and complete cDNA sequences." Supporting this position, the Examiner refers to a GenBank record published after Applicants' filing date that describes an uncharacterized cDNA from the NEDO cloning effort having similarity to mouse kanadaptin and to the claimed kanadaptin homologue. The NEDO cDNA is larger than the claimed nucleic acid molecule. Applicants respectfully traverse.

Claim 7 has been cancelled without prejudice, thereby obviating the rejection as to that claim. With respect to the presently pending claims, Applicants assert that the pending "isolated polynucleotide" claims are not intended to encompass the entire genus referred to be the Examiner. In particular, the claims are not intended to encompass gene sequences (*i.e.*, genomic DNA). Throughout the instant specification, in the instances where Applicants refer to isolated polynucleotides, it is in the art-recognized context of an isolated DNA molecule (*e.g.*, a cDNA), an isolated plasmid, isolated probe sequences, isolated vector components (*e.g.*, regulatory sequences) and the like. Contrast this with the instant specification at page 257 lines 12-24 wherein it is stated that "the invention ***also*** provides genes ***corresponding*** to the cDNA sequences disclosed herein". A detailed definition is provided for corresponding genes and/or genomic sequences. It is clear from Applicants' distinct use of the terms "isolated polynucleotide" and "corresponding gene" that the two terms do not have coextensive meaning. In view of Applicants' distinct usage of the terms "isolated polynucleotide" and "corresponding gene" in the instant specification, one of ordinary skill in the art would readily appreciate that isolated

polynucleotides are distinguished from genes that correspond said sequences in that the latter are polynucleotides which have been isolated away from genomic sequences. Therefore, based on the instant specification, one of ordinary skill in the art would understand that the term "isolated polynucleotide" as used in the instant claims does not encompass genomic DNA.

Moreover, the claims have been amended (and new claims have been added) to encompass only a defined subset of all polynucleotide sequences including, for example, polynucleotides that have a significant degree of sequence identity, or hybridize with, and share activity with the sequences of clone er311_20, fusion polynucleotides and the like. It is Applicants' position that the instant specification, in view of the vast knowledge of the skilled artisan at the time of the invention, provides adequate written description of the genus encompassed by the presently pending claims.

Applicants cloned and sequenced a novel human homologue of mouse kanadaptin, setting forth a full open reading frame (ORF) and predicted amino acid sequence as SEQ ID NOs: 21 and 22, respectively. The ORF set forth as SEQ ID NO:21 was judged by the instant inventors to be a full ORF by a variety of art-recognized criteria and would be predicted to comprise sufficient sequence information to encode a variety of kanadaptin homologue activities based, at least in part, on the fact that the homologous sequences for all of the active mouse sequence are contained within the identified ORF. The 91kDa band detected by Applicants following COS cell transfection evidences that Applicants' cDNA encodes expressable protein. Notably it is only the er311_20 sequence (encoding 667 amino acids) that was transfected into COS cells to express the polypeptide having an apparent molecular weight of 91kDa . That the predicted molecular weight and apparent molecular weight on polyacrylamide gels differ is routine in the art and is very likely due to post-translational modification of the expressed protein. Applicants refrain from commenting on whether the GenBank record cited by the Examiner sets forth an additional or alternative kanadaptin homologue ORF.

It suffices to say that Applicants' ORF includes sufficient kanadaptin homologue coding sequences, in particular, when compared to the previously characterized mouse kanadaptin sequences. Accordingly, a genus of polynucleotides including fusion polynucleotides, polynucleotides with a significant degree of sequence identity and/or sequences that would hybridize under the high stringency conditions recited in the presently pending claims would be readily apparent to the skilled artisan. In view of the foregoing, Applicants assert that they were indeed in possession of the claimed isolated polynucleotides at the time the invention was made, and therefore request reconsideration and withdrawal of the rejection.

Claim Rejections – 35 USC § 102

Claims 1-5, 7 and 8 stand rejected under 35 U.S.C. 102(b) as being anticipated by PCT publication number WO9845436 (published 15 October 1998) by LaVallie, E. *et al.* Applicants traverse the rejection.

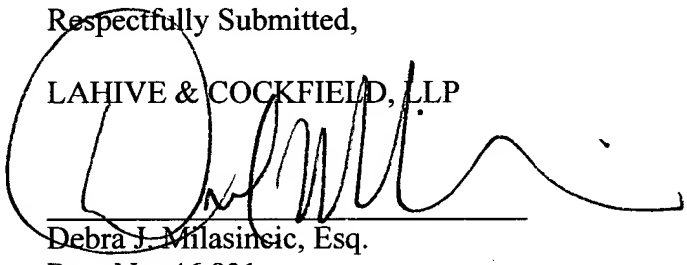
Claim 7 has been cancelled without prejudice, thereby obviating the rejection as to that claim. With respect to the presently pending claims, Applicants direct the Examiner's attention to the fact that LaVallie *et al.* was published ***after*** June 2, 1998, the 35 U.S.C. 120 priority date of the instant claims. Applicants cloned er311_20 and described the clone in U.S. Serial No. 60/087,645 filed June 2, 1998. Clone er311_20 was deposited with the American Type Culture Collection as Accession No. 98781 on June 2, 1998 under the terms of the Budapest Treaty. Therefore, LaVallie *et al.* is unavailable as prior art against the instant application as it was published ***after*** the priority date of the instant claims. In view of the above, Applicants respectfully request that the Examiner withdraw the rejection of claims 1-5, 7 and 8 under 35 U.S.C. §102(b).

SUMMARY

Entry into the record of the application of the foregoing new claims and claim amendments and remarks, reconsideration and withdrawal of all the rejections, and allowance of this application with all pending claims are respectfully requested. If a telephone conversation with Applicants' Attorney would expedite the prosecution of the above-identified application, the Examiner is urged to call (617) 227-7400.

Respectfully Submitted,

LAHIVE & COCKFIELD, LLP



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Dated: **November 5, 2001**

APPENDIX A
VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Specification:

The paragraph beginning at page 1, line 5, has been replaced with the following rewritten paragraph:

This application [is a continuation-in-part] claims the benefit of the following applications:

(1) provisional application Ser. No. 60/084,564, filed May 7, 1998;

(2) provisional application Ser. No. 60/087,645, filed June 2, 1998;

(3) provisional application Ser. No. 60/093,712, filed July 22, 1998;

(4) provisional application Ser. No. 60/094,935, filed July 31, 1998;

(5) provisional application Ser. No. 60/095,880, filed August 10, 1998;

(6) provisional application Ser. No. 60/096,068, filed August 11, 1998;

all of which are incorporated by reference herein.

In the Claims:

Claims 1, 2, 5 and 8, have been amended as follows:

1. (Amended) An isolated polynucleotide comprising [a nucleotide sequence selected from the group consisting of:

(a)] the nucleotide sequence of SEQ ID NO:21[;

(b) the nucleotide sequence of SEQ ID NO:21 from nucleotide 8 to nucleotide 2008;

(c) the nucleotide sequence of the full-length protein coding sequence of clone er311_20 deposited under accession number ATCC 98781;

(d) a nucleotide sequence encoding the full-length protein encoded by the cDNA insert of clone er311_20 deposited under accession number ATCC 98781;

(e) a nucleotide sequence encoding a protein comprising the amino acid sequence of SEQ ID NO:22;

(f) a nucleotide sequence encoding a protein comprising a fragment of the amino acid sequence of SEQ ID NO:22, the fragment comprising eight contiguous amino acids of SEQ ID NO:22;

(g) the nucleotide sequence of a polynucleotide that hybridizes under conditions at least as stringent as 4X SSC at 65 degrees C, or 4X SSC at 42 degrees C with 50% formamide, to any one of the polynucleotides specified by (a)-(d); and

(h) the nucleotide sequence of a polynucleotide that hybridizes under conditions at least as stringent as 4X SSC at 50 degrees C, or 6X SSC at 40 degrees C with 50% formamide, to any one of the polynucleotides specified by (a)-(d), and that has a length that is at least 25% of the length of SEQ ID NO:21].

2. (Amended) The polynucleotide of any one of claims 1, 8 or 14-19, [claim 1] wherein said polynucleotide is operably linked to at least one expression control sequence.

5. (Amended) A process for producing a protein encoded by the polynucleotide of [claim 2] any one of claims 1, 8 or 14-19, which process comprises:

(a) growing a culture of a host cell transformed with [the] said polynucleotide [of claim 2] in a suitable culture medium; and

(b) purifying said protein from the culture.

8. (Amended) [The polynucleotide of claim 7, wherein the polynucleotide comprises] An isolated polynucleotide comprising the cDNA insert of clone er311_20 deposited under accession number ATCC 98781.